

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants: C. David SHOOK et al.

Title: UNDERSTOCKING WITH SLEEVE FOR POSITIONING A GEL PAD

Filing Date: June 25, 2003

Serial No. 10/603,643

Examiner: Camtu Tran NGUYEN

Group Art Unit: 3743

Attorney Docket No. 8142A

September 14, 2007

Commissioner for Patents
P. O. Box 1450
Alexandria, Va. 22313-1450

SECOND APPEAL BRIEF

In response to the July 31, 2007 final office action rejecting all claims 1-19 and 21-24, applicant responds as follows. No claim stands allowed. Claim 20 was previously cancelled.

A Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences is being filed contemporaneously herewith.

This application (and previously rejected claims) was previously appealed and fully briefed by the applicants and the Primary Examiner. A new ground of rejection was

cited by the Primary Examiner and prosecution was reopened with amendments to some of the claims and a final rejection issued by the Primary Examiner on July 31, 2007 rejecting all of the claims.

REAL PARTY IN INTEREST

The real parties in interest are C. David Shook and David J. Hoy.

RELATED APPEALS AND INTERFERENCES:

There are no other appeals or interferences which will directly affect or have a bearing on the Board's decision in this pending appeal. Prosecution was re-opened following the Examiner's citation of a new ground of rejection in the previous appeal of the rejected claims of the subject patent application serial no. 10/603,643.

STATUS OF THE CLAIMS:

Claims 1-19 and 21-24 have been finally rejected, are under appeal, and are found in the attached appendix. An after-final amendment is filed contemporaneously herewith to correct claim 22 and to put it into a condition for appeal. Claims 17 and 24 have been amended to correct the grammar thereof.

STATUS OF AMENDMENTS

An after-final amendment is filed contemporaneously herewith to correct claim 22 and to put it into a condition for appeal. Claims 17 and 24 have been amended to correct the grammar thereof.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 1 recites a stocking comprising a sleeve and a moldable gel pad within the sleeve. Reference is made to the specification page 3, line 14 et. seq., page 7, lines 1-10, page 8, lines 1-11, and Fig. 4, a view of an understocking illustrating the sleeve in which the moldable gel pad resides. Support for the amendment including the word “moldable” in the various claims is found on page 3 line 8 wherein it is stated that this “gel molds under the stocking to fill in depressions around the malleolus.”

Fig. 1 is a top view 100 of the moldable gel pad 101 which shows the moldable gel pad with a seal 102 which holds the amorphous gel and the plastic seal border 103 which surrounds the moldable gel pad.

The sleeve is formed by an outer portion 401 and an inner portion 401A. Fig 4. shows an understocking 400 illustrating an opening 402 to a sleeve 708 which extends around most of the stocking. Sleeve 708 is defined by sock surfaces 401/401A. The understocking may optionally be a compression stocking or a graded compression stocking. The understocking has sufficient elasticity to secure the moldable gel pad 101 in place.

In regard to claim 2, a stocking as claimed in claim 1 is recited wherein the sleeve has an opening for accessing, placing, and positioning gel pad within the sleeve. Fig. 4 illustrates an opening 402 to a sleeve 708 which extends around most of the stocking.

Claim 3 recites and claims a compression stocking comprising a sleeve and a moldable gel pad within the sleeve. Fig. 10 shows the compression stocking 1001 over

the entire understocking as well as the sleeve. The sleeve is formed by an outer portion 401 and an inner portion 410A. Stitching 403 secures inner portion 401A to the outer portion 401. End of understocking 404 is a portion of the understocking which is folded over and onto itself to form the portions 401/401A. The compression stocking is placed over the entire understocking. The understocking holds the moldable gel pad in position. Reference is made to the specification page 7 lines 18-21; page 10, lines 16-21; page 11, lines 1-4; page 11, line 21, lines 1-4 and line 21; and page 12, lines 1-2 and lines 9-11.

In regard to claim 4, a compression stocking as claimed in claim 3 is recited wherein the sleeve has an opening in said sleeve for accessing, placing, and positioning the gel pad within the sleeve.

In regard to claim 5, a stocking as claimed in claim 2 is recited wherein the stocking includes a folded portion and a stitched portion 403 to form the sleeve. See specification page 7, lines 8-10.

In regard to claim 6, a compression stocking as claimed in claim 4 is recited wherein the compression stocking includes a folded portion and a stitched portion to form the sleeve.

In regard to claim 7, a stocking as claimed in claim 5 is recited wherein the sleeve extends 360 degrees within the stocking. See Fig. 7 which illustrates the sleeve extending 360 degrees around the stocking. See page 7, lines 11-14 of the specification.

In regard to claim 8, a compression stocking as claimed in claim 6 is recited

wherein the sleeve extends 360 degrees within the stocking.

Claim 9 recites a device for treating venous insufficiency comprising an understocking having a sleeve and a moldable gel pad within the sleeve. Reference is made to the specification page 3, lines 14 et. seq. and Fig. 4, a view of an understocking illustrating the sleeve in which the moldable gel pad resides.

In regard to claim 10, a device for treating venous insufficiency as claimed in claim 9 is recited wherein the sleeve has an opening for accessing, placing, and positioning the moldable gel pad within the sleeve. Fig. 4 illustrates an opening 402 to a sleeve 708 which extends around most of the stocking.

In regard to claim 11, a device for treating venous insufficiency as claimed in claim 10 is recited comprising a compression stocking residing over the overstocking. Fig. 10 shows the compression stocking 1001 over the entire understocking as well as the sleeve. The sleeve is formed by an outer portion 401 and an inner portion 410A. Stitching 403 secures inner portion 401A to the outer portion 401. End of understocking 404 is a portion of the understocking which is folded over and onto itself to form the portions 401/401A. The compression stocking is placed over the entire understocking. The understocking holds the moldable gel pad in position.

In regard to claim 12, a device for treating venous insufficiency as claimed in claim 9 is recited wherein a compression stocking resides over the understocking. Fig. 10 shows the compression stocking 1001 over the entire understocking. Reference is made to

the specification page 7, lines 18-21, page 10, lines 16-21, page 11, lines 1-4, and page 12, lines 1-2.

In regard to claim 13, a device for treating venous insufficiency as claimed in claim 9 is recited wherein the understocking includes a folded portion and a stitched portion forming the sleeve. See specification page 8, lines 8-10.

In regard to claim 14, a device for treating venous insufficiency as claimed in claim 13 is claimed wherein the understocking is made from a material selected from the group of nylon, polyester, and cotton. See specification page 8, lines 4-5.

In regard to claim 15, a device for treating venous insufficiency as claimed in claim 13 is claimed wherein the understocking is made from a material selected from an elastic material. See specification page 8, lines 5-6.

Claim 16 recites a method of treating a patient having venous insufficiency comprising the steps of: applying an understocking having a sleeve onto the foot, ankle and leg of the patient; inserting a moldable gel pad into the sleeve; and, positioning the moldable gel pad about the foot, ankle and leg of said patient to apply pressure to reduce the venous insufficiency. See specification page 10, lines 5 et. seq.

In regard to claim 17, a method of treating a patient having venous insufficiency as claimed in claim 16 is recited further comprising the steps of: applying a compression stocking over the understocking and moldable gel pads. See specification page 10 lines 13 et. seq.

In regard to claim 18, a method of treating a patient having venous insufficiency as claimed in claim 16 is recited wherein the understocking is a compression stocking. See specification page 10, lines 13 et. seq.

In regard to claim 19, a method of treating a patient having venous insufficiency as claimed in claim 17 is recited wherein the understocking is a compression stocking. See specification page 10 lines 13 et. seq.

Claim 20 has been cancelled.

In regard to claim 21, a stocking as claimed in claim 1 is recited where a moldable gel pad is comprised of a material that is soft and pliable.

In regard to claim 22, a stocking as claimed in claim 2 is recited wherein stocking fits over a bodily appendage and the moldable gel pad is small and thin, and moldable gel pad is fit into surface contours of a bodily appendage.

In regard to claim 23, a compression stocking as claimed in claim 3 wherein the stocking is placed over a bodily appendage to provide the desired distribution of pressure between the compression stocking and the bodily appendage.

In regard to claim 24, a stocking for use in combination with a bodily appendage where the moldable gel pad is positioned in proximity to surface irregularities of the bodily appendage.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Issue 1. Did the Examiner correctly reject Claim 22 under 35 USC 112, ¶1?

Issue 2. Did the Examiner correctly reject Claims 1, 2, 5, 7, 9-15, 22 and 24 under 35 USC 103 (a) as being unpatentable over Knox et al. (U.S. Patent No. 5,814,003) further in view of Sabin et al. (U.S. Patent No. 5,984,953)?

Issue 3. Did the Examiner correctly reject Claims 1, 2, 5, 7, 9-15, 22 and 24 under 35 USC 103 (a) as being unpatentable over Knox et al. (U.S. Patent No. 5,814,003) further in view of Beisang, III et al. (U.S. Patent No. 4,596,250)?

Issue 4. Did the Examiner correctly reject Claims 1-6, 8-19 and 21- 24 under 35 USC 103 (a) as being unpatentable over Gold (U.S. Patent No. 5,187,814) and further in view of Sabin et al. (U.S. Patent No. 5,984,953)?

Issue 5. Did the Examiner correctly reject Claims 1-6, 8-19, and 21- 24 under 35 USC 103 (a) as being unpatentable over Gold (U.S. Patent No. 5,187,814) and further in view of Beisang III et al (U.S. Patent No. 4,596,250)?

Issue 6. Did the Examiner correctly reject Claim 7 under 35 U.S.C. 103(a) as being unpatentable over Gold (United States Patent 5,187,814), modified by Sabin, et al (U.S. Patent No. 5,984,953), and further in view of Lyles (United States Patent 6,001,122)?

Issue 7. Did the Examiner correctly reject Claim 7 under 35 U.S.C. 103(a) as being unpatentable over Gold (United States Patent 5,187,814), modified by Beisang, III,

et al (U.S. Patent No. 4,596,250), and further in view of Lyles (United States Patent 6,001,122)?

Argument

Issue 1: Did the Examiner correctly reject Claim 22 under 35 USC 112, ¶1?

Applicants agree with the Examiner and have submitted an after-final amendment filed contemporaneously herewith to correct claim 22 and to put it into a condition for appeal. Claim 24 has been amended to correct the grammar thereof.

Issue 2: Whether or not the rejection of Claims 1, 2, 5, 7, 9-15, 22 and 24 is correct under 35 USC 103 (a) as being unpatentable over Knox et al. (U.S. Patent No. 5,814,003) in view of Sabin et al. (U.S. Patent No. 5,984,953)?

Applicants respectfully traverse this rejection.

Issue 2, Claims 1 and 2

Knox et al (U.S. Patent No. 5,814,003 hereinafter “Knox”) discloses a device for positioning a pulsatile bladder about a portion of a user’s body. The Primary Examiner states at page 4 of the final office action of July 31, 2007 that:

“Knox et al. discloses in Fig. 2 [an] anti-embolism stocking comprising elements recited in these claims including a pocket (16). The Knox et al device is capable of holding a moldable gel pack, such as Sabin et al’s gel pack.”

Knox consists of an inner sleeve and an outer sleeve extending over the inner sleeve. Knox does not disclose a moldable gel pad. Knox also does not disclose or teach the positioning of the moldable gel pad within the sleeve. Knox appears to be worn

somewhat high on the leg and is of questionable value to a person needing pressure applied equally to the concavities about a person's ankle.

Sabin et al (U.S. Patent No. 5,984,953 hereinafter "Sabin") discloses a self-heating, disposable heating pack which utilizes an exothermic chemical reaction. The temperature of the heat pack is altered with the use of an exothermic chemical reaction and evaporation of a solvent. There is no disclosure of pressure or compression in Sabin. The heat pack changes in stiffness and can not be stably held in a stocking. Sabin's heat pack which is stiff cannot mold to fit the recesses which are located about an ankle. The moldable gel pad of the claimed invention cannot be replaced by a stiff heat pack which necessarily gives off heat. Further, the heating pack in Sabin is sealed and undergoes a phase transformation. This structure can be not considered moldable because the outer dimensions are not designed to change and further the package is designed, to maximize the contact area of the inner contents so that they can be mixed. Further, as a result of these liquid contents which undergo a chemical reaction, this sealed heat pack is not designed to withstand pressure or be placed close to the skin under pressure without causing burns.

Knox and Sabin lack the claimed moldable gel pad

Neither Knox nor Sabin disclose a moldable gel pad. Claim 1 recites a moldable gel pad in a sleeve of a stocking. Knox has a pulsatile bladder with fluid such as air being pumped into it. The pulsatile bladder is not a moldable gel pad. The Examiner is

attempting to equate a pulsatile bladder with a moldable gel pad and they are not the same. Further, both references lack any teaching, suggestion, or motivation toward a pad. Knox discloses a pulsatile device which pulses when pumped with air and Sabin is a heat pack which changes in both temperature and stiffness.

Would a person of ordinary skill in the art, i.e., a clinician or physician, look to ripping the bladder out of Knox et al. and replacing it with a stiff heat pack of Sabin which may be inadvertently activated to give off heat somehow to become stiff? Would the person of ordinary skill in the art believe that heating an ulceration is desirable in some fashion for the treatment of the wound?

The heat pack of Sabin releases heat and is not a moldable gel pad--it is a heating device which stiffens when the separator is opened. It is not designed to be malleable and fit close to the skin. The pack in Sabin is not moldable. The word "moldable" does not appear in the Sabin specification. This device of Sabin contains separate packs of liquids which stiffen once activated. Following activation, which may be inadvertent if the separator is compromised, the heater pack has a dramatic rise in temperature and the heat pack stiffens. The separator may be compromised if the heat pack is somehow bent in an attempt to make it fit the curvature of a patient's body. Sabin's heater pack device includes liquid and stiffens while increasing in temperature upon activation of the separator. Sabin's heat pack changes its characteristics and is not useable as a moldable gel pad in any way. As temperature increases in the Sabin heat pack, stiffness increases

which makes moldability difficult or impossible. Both Knox et al and Sabin lack a moldable gel pad.

Further, the references are not properly combinable. There is no teaching, suggestion, or motivation for a person of ordinary skill in the art to combine the anti-embolism stocking of Knox with a heater pack of Sabin. Knox uses a pulsatile bladder to prevent embolisms or clots. Sabin identifies several ailments which can be treated with heat in Col. 17, line 38 et. seq. including muscle and ligament strains, rheumatism, arthritis, but embolisms are not named to make combinable with Knox reference. Venous insufficiency is not named or mentioned in either reference. The heater pack of Sabin is not properly combinable with a pulsatile bladder of Knox.

Sabin's goal is to transfer heat and it may be held onto a person's skin by straps using Velcro or with tape. Tape or Velcro is required because as the heat is given off the stiffness of the pack increases and wants to elongate. Some strong force such as Velcro or the straps is necessary to hold the heater pack in place. Sabin, col. 17, lines 13 et seq. Sabin goes on to say that the heat packs may be formed as a sleeve or that flat heat packs can be inserted into a fabric sleeve. Still further, Sabin states that the packs can be formed as a pad where large body surfaces such as those on the back of a person can be heated.

The pulsatile/bladder of Knox will not fill in a crevice or recess adjacent to a bony prominence like those that exist in proximity to an ankle. The heat pack of Sabin releases

heat and is not a moldable gel pad. It is not designed to either be malleable or fit close to the skin which transfers the pressure of the outer portion of the stocking to the patient's skin to reduce venous insufficiency as in the claimed invention. (See paragraph 15 of the Shook et al 20040158283 A1 Publication). Both references lack a moldable gel pad structure.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. 'The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.' Here, it is respectfully suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the references to arrive at the instant invention as claimed. However, even if they were to be combined they would not result in the structure as claimed.

Flat heat packs of Sabin which stiffen do not meet claims 1 and 2 which recite a "moldable gel pad." Flat packs of Sabin within the sleeve of Knox would not fill the depressions around the ankle of a person. Claim 1, although admittedly broad, is, in fact,

patentable over Knox and Sabin.

Claim 2 is dependent on claim 1 and is allowable for at least the reasons that claim 1 is allowable.

Issue 2, Claim 5

Claim 5 recites a stocking including a folded portion and a stitched portion to form a sleeve. The folded and knit portions bound the sleeve in the instant application. Knox and Sabin lack this structure. Knox in view of Sabin lack this structure having a folded portion. Further, Knox and Sabin do not provide any teaching, suggestion, or motivation to form a sleeve in stocking with a folded portion. Knox in view of Sabin does not render the instant application obvious and claim 5 is believed to be allowable.

Issue 2, Claim 7

Claim 7 is allowable for its dependence on claim 5 and its indirect dependence on claim 2 which is also allowable. Claim 7 recites the following structure which is not found in Knox in view of Sabin: a sleeve which extends 360 degrees within the stocking. Both Knox and Sabin lack a sleeve which extends 360 degrees within a stocking. Sabin does not have a stocking. Further, Knox has transitional stitches 26 extending downwardly the juncture of inner and outer layers which interrupt the sleeve from extending 360 degrees within the stocking. Further, Knox also has a turned welt 28 and foot portion 28 which also interrupts the sleeve from completely extending 360 degrees within the stocking.

Issue 2, Claim 9

Claim 9 recites a device for treating venous insufficiency comprising an understocking having a sleeve and a moldable gel pad within the sleeve. Knox in view of Sabin lack the sleeve, a moldable gel pad within the sleeve, and an understocking. Knox completely lacks a moldable gel pad and any teaching, suggestion, or motivation towards a moldable gel pad. Sabin also lacks a moldable gel pad. Sabin has a heater pack. This structure is large, and when activated it becomes stiff and increases in temperature. This structure in Sabin is not compatible with applications where a pad is required due to the increased stiffness it exhibits. Neither reference contains the word “moldable” in their specification. Further, there is no teaching, suggestion, or motivation in either reference that would allow one of ordinary skill in the art to combine the references to result in the structure as claimed.

The Knox reference teaches away from recited elements of claim 9 as the outer sleeve is less elastic to accommodate the bulky pulsatile bladder and tubing. This sleeve structure could not be used as an understocking due to its bulky size. Further there is no teaching, suggestion, or motivation in Knox in view of Sabin for any additional structure to fit over it. The device of Knox in view of Sabin teaches away from this as it requires spacing i.e. a loose fitting outer elastic layer to allow for movement of the pulsatile device and the tubing. Additionally, in Col. 4, line 52, Knox states explicitly that the sleeve is designed so that the contents are not pressed uncomfortably against the wearer’s skin.

This disclosure of a loose outer sleeve and contents not pressing against the wearer's skin directly teaches away from the instant application as a device for treating venous insufficiency. As a result, claim 9 is not made obvious by Knox in view of Sabin.

Issue 2, Claim 10

Claim 10 is dependent on claim 9 and is allowable at least for the reasons stated above as well as for the additional elements of claim 10. Claim 10 recites a device for treating venous insufficiency comprising an opening for accessing, placing, and positioning a moldable gel pad within the sleeve. As the heat pack in Sabin and the pulsatile bladder and required tubing are both large, they are placed and positioned around the circumference of the wearer's limb (See Col. 4, line 58-59 of Knox and Col. 17, lines 12-24 of Sabin). There is no teaching in Knox in view of Sabin for positioning a moldable gel pad within the sleeve as the structures of both Knox and Sabin are large and the structure of Knox in view of Sabin would consume the space in the sleeve and could not be positioned within the sleeve. Both references teach positioning the entire sleeve about the circumference of the wearer's limb. But there is no teaching concerning positioning either of these devices within the sleeve.

Further, it would not be possible to apply pressure with the device of Knox in view of Sabin because these devices are too large to transfer pressure to a small section of an appendage in order to treat the venous insufficiency. There is no teaching, suggestion, or motivation in either reference to treat a venous insufficiency using a moldable gel pad

according to either one of these references whether used alone or in combination.

Further, because both the heat pack and the pulsatile bladder structures of the references are much larger they could not be placed within the sleeve of an understocking to apply pressure to a small area necessary to treat venous insufficiency. As a result, claim 10 is believed to be allowable and is not made obvious by Knox in view of Sabin.

Issue 2, Claim 11

Claim 11 recites a compression stocking comprising a sleeve and a moldable gel pad which is not disclosed in either reference. Knox discloses an inner wall of a sleeve which is a compression stocking. Knox does not disclose a moldable gel pad which is held in place by an outer wall of a sleeve to enable the user to pull a compression stocking thereover.

Knox specifically teaches away from this claimed structure of the instant invention by stating that in Col 2, lines 48-55: “ The stocking desirably includes an inner tubular sleeve and an outer tubular sleeve which is relatively less elastic than the inner sleeve. Further, because the outer layer 14 is less elastic than the inner layer 12, the tendency for the bladder 22 to be pressed uncomfortably against a wearer’s limb by the stocking 10 is reduced.” As a result, Knox teaches away from the claimed invention where the moldable gel pad is held in position by the outer portion of the sleeve to enable the user to pull a compression stocking thereover. Sabin also lacks a compression stocking and a moldable gel pad.

Claim 11 is dependent on claim 10 and indirectly dependent on claim 9 and is allowable at least for the reasons that both claims 9 and 10 are allowable. Further, claim 11 recites a compression stocking residing over the understocking having a moldable gel pad within a sleeve of the understocking. Knox discloses a graduated compression inner stocking, but does not disclose a graduated compression stocking over the understocking. The claimed outer compression stocking is totally missing from both Knox and Sabin and from the combination of Knox in view of Sabin. As discussed above in connection with claim 1, the moldable gel pad is missing from both references, and, as a result a prima facie case of obviousness has not been made and claim 11 is believed to be allowable.

Further, there is no teaching, suggestion, or motivation in either reference to insert either the large anti-embolism pulsatile device of Knox, the large heat pack of Sabin, or device of Knox in view of the device of Sabin into a compression stocking. Most importantly, both references have structural elements that are not properly combinable with a compression stocking and teach away from the compression stocking structure to treat a venous insufficiency. As the pulsatile bladder of Knox requires a loose fitting outer layer to allow for movement, there would be no reason for combining a pulsatile bladder with a compression stocking. Secondly, the heat pack of Sabin is not properly combinable with a compression stocking as the heat of this device in combination with high pressure of a compression stocking could result in a severe burn to the skin, damage to the ulceration, and/or stiffening or flattening of the heat pack of Sabin pulling it away from

the cavities where its treatment is needed most.

There is no reason a person of ordinary skill in the art would look to combine Knox and Sabin to arrive at the structure as claimed.

Further, Knox with a pulsatile bladder, and Sabin with various reactive constituents which require large surface areas in order to be mixed effectively, have size requirements that would make it difficult to fit in an understocking or to pull a compression stocking over them. There is no teaching, suggestion, or motivation that would allow one of ordinary skill in the art to pull a compression stocking over an understocking which contains either of these structures.

As a result, claim 11 is believed to be allowable for the reasons stated above as well as for its dependence on claims 9 and 10.

Issue 2, Claim 12

Claim 12 is directly dependent on claim 9 and is allowable for at least the reasons that claim 9 is allowable. Claim 12 like claim 11 recites a compression stocking over the understocking. Claim 12 is allowable for the same reasons stated above in regard to claims 11 and 9.

Issue 2, Claims 13, 14, and 15

Claims 13, 14, and 15 require an understocking having folded and stitched portions. Claim 13 recites a sleeve formed from a folded portion. Claim 14 is dependent on claim 13 and requires an understocking made from the group of materials selected

from nylon, polyester, and cotton. Knox does not disclose nylon, polyester or cotton.

Claim 15 recites an understocking made from an elastic material. Knox and Sabin lack an understocking having a folded portion which forms the sleeve. Knox in view of Sabin does not disclose all the elements or limitations of claims 13, 14, and 15. Applicant believes that a proper prima facie case of obviousness has not been made.

As a result, Knox in view of Sabin and claims do not render claims 13-15 obvious.

Issue 2, Claim 22

Claim 22 is dependent on claim 2 and is allowable for at least the reasons that claims 1 and 2 are allowable. Claim 22 has further limitations that are not found in Knox in view of Sabin. Claim 22 recites a stocking which fits over a bodily appendage where the bodily appendage has an exterior surface with surface contours. Claim 22 further recites a moldable gel pad which is small and thin and fits in the surface contours of the bodily appendage.

Knox in view of Sabin lack the claimed small, thin, moldable gel pad as stated above. Sabin has a heat pack with liquid contents that require a large surface area in order to be mixed properly. This teaches away from the structure of the instant invention of a gel pad which is small and thin. Sabin, in particular, describes using the heating device on a large exterior surface of the body such as the back or the chest. (See Knox Col. 4, lines 56-61 and Sabin Col. 17, line 25). Knox also requires larger structure as the pulsatile bladder described in Knox is designed to have air pulsed through it and would not be

considered small or thin. There is no teaching, suggestion, or motivation found in Knox in view of Sabin that would result in the claimed structure.

In fact, both Knox and Sabin teach away from a small, thin moldable gel pad which is capable of fitting in a bodily appendage. Sabin has large separate zones with liquid contents to produce an exothermic reaction resulting in a stiff pack. Knox has a large anti-embolism device which according to the specification is designed not to be pressed against the skin.

Based on the reasons stated above, and for the reasons that claims 1 and 2 are allowable, claim 22 is not made obvious by Knox in view of Sabin, and is allowable.

Issue 2, Claim 24

Claim 24 recites a stocking for use in combination with a bodily appendage where the stocking includes a compartment with a moldable gel pad and the moldable gel pad is placed in proximity to the surface irregularities of the bodily appendage. Knox in view of Sabin does not provide any teaching, suggestion, or motivation to place a moldable gel pad in proximity to surface irregularities of a bodily appendage. Both the pulsatile bladder device of Knox and the heater device in Sabin have teachings to locate these large devices on the outer circumference of a bodily appendage. There is no teaching, suggestion, or motivation found in either reference or in Knox in view of Sabin to arrive at the structure as claimed. Claim 24 is not made obvious by Knox in view of Sabin. As a result, claim 24 is believed to be patentable.

Issue 3

Whether or not the rejection of Claims 1, 2, 5, 7, 9-15, 22 and 24 is correct under 35 USC 103 (a) as being unpatentable over Knox et al. (U.S. Patent No. 5,814,003) further in view of Beisang, III et al. (U.S. Patent No. 4,596,250)?

Issue 3, Claims 1 and 2

Knox et al. (U.S. Patent No. 5,814,003 hereinafter “Knox”) discloses a device for positioning a pulsatile bladder about a portion of a user’s body as discussed above in regard to the previous rejection. Knox discloses an inner sleeve and an outer sleeve extending over the inner sleeve. Knox does not disclose a moldable gel pad. Knox also does not disclose or teach the positioning of the moldable gel pad within the sleeve.

Beisang, III et al.(U.S. Patent No. 4,596,250 hereinafter “Beisang”) discloses a cold/heat pack comprising a layer of silicon rubber, a polymer film layer, and a metal-coated layer. The cold/heat pack contains a mixture of phase change chemicals including: water, propylene glycol, various polysaccharides to form a temperature storage material. Beisang’s heat pack changes in stiffness and temperature. Beisang’s cold/heat pack which is designed to become stiff at cold temperatures below -17 °C cannot mold to fit the recesses which are located about an ankle.

Beisang’s invention is directed primarily to cooling organs of a human body so that they can be treated. As it is known that cooling an organ slows its metabolism and enables more effective treatment of the organ and the patient. So, Beisang enables this by

providing a moldable pillow type device that can hug the shape of an organ to be operated on during surgery without taking energy away from the other organs. Further, with Beisang it is necessary that the temperature be controlled so that the patient doesn't in effect get freezer burn.

Beisang is essentially a hot water bottle with one stiff side which thermally non-conductive and one moldable side which thermally conductive and moldable when it is not frozen.

Claim 1 recites a moldable gel pad of the claimed invention which is not met by the stiff cold/heat pack of Beisang. Beisang mentions in passing that his pillow-shape device can be used on ankles and elbows. However, Beisang's device is not believed suitable for use in cold weather as it may freeze reducing its moldability.

The cold/heat pack in Beisang is sealed and undergoes a phase transformation and can not be considered moldable because the outer shape is not designed to change. Further, Beisang is designed to maximize the contact area of the inner contents so that they can be mixed. As a result, when these liquid contents undergo a chemical reaction, Beisang can not be placed close to the skin under pressure due to the risk of the patient being burned.

Knox and Beisang lack the claimed moldable gel pad

Further, neither Knox nor Beisang disclose a moldable gel pad. Claim 1 recites a moldable gel pad in a sleeve of a stocking. Knox has a pulsatile bladder with fluid such as

air being pumped into it. The pulsatile bladder is not a moldable gel pad.

The cold/heat pack of Beisang releases heat and is not a moldable gel pad. Beisang contains separate packs of liquids which stiffen when cooled. Following activation, the cold/heat pack has a rise in temperature and becomes moldable. Beisang's device is designed to have unidirectional heat transfer capabilities, so that heat is conserved from the side of the device not facing the organ to be operated on.

Further, Beisang illustrations show a rectangular pillow-like configuration (Col. 3, lines 6-7) as one example. Beisang has a surface that faces an organ during surgery and which is somewhat moldable on one side thereof at certain temperatures. Beisang's heat/cool pack is designed to cool an organ during surgery and it is respectfully submitted that it is at best a one sided somewhat moldable device at certain temperatures which is not reasonably insertable in a sleeve within a stocking. It is respectfully submitted that in cold weather -17°C, assuming arguendo, that Beisang's device is inserted in place of the pulsatile bladder of Knox, it would freeze up and cease to be operational because it would be rock hard.

Further, the references are not properly combinable. There is no teaching, suggestion, or motivation for a person of ordinary skill in the art to combine the anti-embolism stocking of Knox with a cold/heat pack of Beisang. Knox uses a pulsatile bladder to prevent embolisms or clots.

Beisang teaches a heating/cooling device designed to be sterilized so that one side

thereof can be placed in direct contact with an organ. Knox discloses a sleeve for carrying a pulsatile anti-embolism on the leg. It is respectfully suggested that a person of ordinary skill in the art would not look to insert a sterilizable heating/cooling pad into a sleeve of a stocking that has no direct contact with an organ. Further, as understood, Beisang's device although perhaps somewhat moldable on one side thereof at certain temperatures to conform to the shape of an organ on one side but heat resistive and rigid on the other side is not believed to be a moldable gel pad within the meaning of the claims of the instant patent application.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. 'The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.' Here, it is respectfully suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the references to arrive at the instant invention as claimed.

Claim 2 is dependent on claim 1 and is allowable for at least the reasons that claim

1 is allowable.

Issue 3, Claim 5

Claim 5 recites a stocking including a folded portion and a stitched portion to form a sleeve. The folded and knit portions bound the sleeve in claim 5 of the instant application. Knox in view of Beisang lacks this structure having a folded portion. As a result, a proper case of prima facie obviousness has not been made. Knox in view of Beisang does not render the instant application obvious and claim 5 is believed to be allowable.

Issue 3, Claim 7

Claim 7 is allowable because of its dependence on claim 5 and its indirect dependence on claims 2 and 1 which are also allowable. Claim 7 recites a sleeve which extends 360 degrees within the stocking and this element is not found in Beisang.

A proper case of prima facie obviousness has not been made, and Knox in view of Beisang does not render the instant application obvious. As a result, claim 7 is patentable.

Issue 3, Claim 9

Claim 9 recites a device for treating venous insufficiency comprising an understocking having a sleeve and a moldable gel pad within the sleeve. Knox in view of Beisang lack an understocking having a sleeve and a moldable gel pad within the sleeve. Knox completely lacks a moldable gel pad and any teaching, suggestion, or motivation toward a moldable gel pad. Beisang also lacks a moldable gel pad as stated above. All of

the arguments made above in connection with Issue 3, Claim 1 are equally applicable here and are incorporated herein by reference without rewriting them herein.

Knox teaches away from this structure as the outer sleeve is less elastic to accommodate the bulky pulsatile bladder and tubing. This sleeve structure could not be used as an understocking as it is bulky and it would be difficult to have any additional structure fit over it. The device of Knox in view of Beisang teaches away from the recited element of the claimed invention as they require spacing i.e. a loose fitting outer elastic layer to allow for movement of the pulsatile device and the tubing. Additionally, in Col. 4, line 52, Knox states explicitly that the sleeve is designed so that the contents are not pressed uncomfortably against the wearer's skin. This disclosure of a loose outer sleeve and contents not pressing against the wearer's skin directly teaches away from the instant application as a device for treating venous insufficiency. As a result, claim 9 is not made obvious by Knox in view of Beisang.

Issue 3, Claim 10

Claim 10 is dependent on claim 9 and is allowable at least for the reasons stated above as well as for the additional structure of claim 10. Claim 10 recites a device for treating venous insufficiency comprising an opening for accessing, placing, and positioning a moldable gel pad within the sleeve. As the heat pack in Beisang and the pulsatile bladder and required tubing of Knox are large they are placed and positioned around the circumference of the wearer's limb (See col. 4, line 58-59 of Knox and col.

17, lines 12-24 of Beisang). There is no teaching in Knox in view of Beisang for positioning a moldable gel pad within the sleeve.

There is no teaching concerning positioning either of these devices within the sleeve. Beisang in particular teaches away from use of a sleeve as Beisang is designed specifically to be in direct contact with an organ. Beisang teaches the surface of the heating/cooling device to be in direct with the organ and to be large so as to maximize thermal transfer and keep the organ cool. In addition, the structure of Beisang is designed for sterilization so that it can be placed in direct contact with an organ. An ordinary person of skill in the art would not look to insert the heating/cooling device of Beisang into a sleeve.

There is no teaching, suggestion, or motivation in either reference to treat venous insufficiency using a moldable gel pad according to either one of these references whether used alone or in combination.

Further, because both the heat pack and pulsatile bladder structures of the references are much larger they could not be placed within the sleeve of an understocking to apply pressure to a small area necessary to treat venous insufficiency. In addition, the pulsatile bladder works on a completely different principle than a moldable gel pad. As a result, claim 10 is believed to be allowable and is not made obvious by Knox in view of Beisang.

Issue 3, Claim 11

Claim 11 is dependent on claim 10 and indirectly dependent on claim 9 and is allowable at least for the reasons that both claims 9 and 10 are allowable. Further, claim 11 recites a compression stocking over the understocking. This structure is totally missing from Knox and Beisang. As a result, applicant respectfully suggests and believes that a proper case of prima facie obviousness has not been made.

Further, there is no teaching, suggestion, or motivation in either reference to pull a compression stocking over an understocking with a large anti-embolism pulsatile or a large heat pack of Beisang in the sleeve of the understocking. Most importantly, both references have structural elements that are not properly combinable to arrive at the claimed invention of, to wit, a compression stocking over an understocking and with a moldable gel pad in a sleeve of the understocking to treat venous insufficiency.

As the pulsatile bladder of Knox requires a loose fitting outer layer to allow for movement, there would be no reason for combining a pulsatile bladder with a compression stocking thereover. Secondly, the heat pack of Beisang is not properly combinable with a compression stocking as the heat of this device in combination with high pressure of a compression stocking could result in a severe burn to the skin of the patient. Beisang specifically states that: “ body tissue can be damaged from too cold or too hot a temperature...” in Col. 3, line 40. It is respectfully suggested that a person of ordinary skill in the art would not be able to combine the structure of Knox and Beisang to arrive at the invention as claimed in claim 11.

As a result, claim 11 is believed to be allowable for the reasons stated above as well as for its dependence on claims 9 and 10.

Issue 3, Claim 12

Claim 12 is dependent on claim 9 and is allowable for at least the reasons that claim 9 is allowable. Additionally, claim 12 recites a compression stocking over an understocking. Claim 12 is allowable for the same reasons stated above in regard to allowable claim 11 which also recites a compression stocking over an understocking. Knox and Beisang as well as Knox in view of Beisang simply lack this structure. As a result, applicant believes that a proper case of prima facie obviousness of claim 11 has not been made.

As a result, Claim 12 is believed to be allowable.

Issue 3, Claims 13, 14, and 15

Claims 13, 14, and 15 require an understocking having a sleeve formed with folded and stitched portions. Claims 13, 14 and 15 are directly or indirectly dependent on claim 9 and are allowable for the same reason that claim 9 is allowable. Claim 13 recites a sleeve formed from a folded portion. Claim 14 is dependent on claim 13. Claim 15 recites an understocking made from an elastic material. Further, both references lack an understocking having a folded portion which form the sleeve. The Knox reference in view of Beisang does not disclose all the elements and limitations of claims 13, 14, and 15.

As a result, claims 13-15 of the instant invention are believed to be allowable.

Issue 3, Claim 22

Claim 22 is dependent on claim 2 and is allowable for at least the reasons that claims 1 and 2 are allowable. Claim 22 has further limitations that are not found in Knox in view of Beisang. Claim 22 recites a stocking which fits over a bodily appendage where the bodily appendage has an exterior surface with surface contours. Claim 22 further recites a moldable gel pad which is small and thin and fits in surface contours of a bodily appendage. Knox in view of Beisang lack any teaching to apply a moldable gel pad in the surface contours of a bodily appendage. Beisang mentions application of a heat pack to an ankle or elbow, but is absolutely silent as to any explanation of how this is done.

The references lack the structure of a moldable gel pad which is small and thin. Both Beisang and Knox recite a large device which is located on the outer circumference of a limb. Beisang has a cold/heat pack with liquid contents that require a large surface area in order to be mixed properly. Both Beisang and Knox have structural requirements which prevent them from being thin or small. This teaches away from the structure of the instant invention of a gel pad which is small and thin. Beisang, in particular, teaches a large surface area to improve thermal transmission with an organ and Beisang requires a large surface area in order to ensure adequate mixture between the liquid contents of the various zones.

Knox also requires larger structure as the pulsatile described in Knox is designed

to have air pulsed through it and would not be considered small or thin. There is no teaching, suggestion, or motivation found in Knox in view of Beisang that would result in the claimed structure.

In fact, both Knox and Beisang teach away from a small, thin moldable gel pad which is capable of fitting in a bodily appendage. Beisang has large separate zones with liquid contents to produce an exothermic reaction. Knox has a large anti-embolism device which according to the specification is designed not to be pressed against the skin. Further, both Knox and Beisang lack a moldable gel pad as discussed above.

Based on the reasons stated above as well as its dependence on claims 1 and 2, claim 22 is not made obvious by Knox in view of Beisang, and is allowable.

Issue 3, Claim 24

Claim 24 recites a stocking for use in combination with a bodily appendage where the stocking includes a compartment with a moldable gel pad and the moldable gel pad is placed in proximity to the surface irregularities of the bodily appendage. Knox in view of Beisang does not provide any teaching, suggestion, or motivation to place a moldable gel pad in proximity to surface irregularities of a bodily appendage. Both the pulsatile bladder device of Knox and the heater device in Beisang have teachings to locate these large devices on the outer circumference of a bodily appendage. There is no teaching, suggestion, or motivation found in either reference or in Knox in view of Beisang to arrive at the structure as claimed. Claim 24 is not made obvious by Knox in view of

Beisang. As a result, claim 24 is believed to be patentable.

Issue 4

Whether or not the rejection of Claims 1-6, 8-19 and 21- 24 under 35 USC 103 (a) is correct as being unpatentable over Gold (U.S. Patent No. 5,187,814) and further in view of Sabin et al. (U.S. Patent No. 5,984,953)?

Gold discloses a heated garment for heating a body part. A pocket assembly is fixed to the garment for receiving the heater pack in a fixed location.

Sabin discloses a self-heating, disposable heating pack. The heat pack stiffens after being activated to release heat when in use.

Claims 1-6, 8-19, and 21-24 disclose structure that is different and not found in Gold or Sabin.

In the last paragraph of page 4, the Examiner states that: " Gold discloses in Figures 6 and 7 a sock (400) with attached heater pack (34) . . . but does not teach a gel pad. Sabin et al discloses a well-known heat pack . . . " Applicant believes the Examiner is correct in stating that Gold does not teach a gel pad. However, on the top of page 5 the Examiner states that . . . "it would have been obvious to one skilled in the art during the time of invention to use the [sic] Sabin et al's gel pack instead as such would be not only environmentally friendly but also economically sound."

Whether this combination could be made is irrelevant, as it would still not result in the structure as claimed. Both references teach the use of a heat pack, but a pack that

supplies heat has nothing to do with the instant invention. A stiff pack that supplies heat in the reference is structurally different from a gel pad that can be compressed safely near the surface of the skin. The invention of the instant application claims a moldable gel pad, both references teach “a pack”, a heat pack is not a moldable gel pad. As a result, the invention of the instant application is not made obvious by Gold in view of Sabin and claims 1-6, 8-19, and 21-24 are patentable.

Further, applicant strongly disagrees with the Examiner’s statement on page 5, line 10. The Examiner states that: ” The Gold device would be capable of performing the method of treating a patient having venous insufficiency via Gold’s sock using Sabin et al’s gel pack.” It would not be possible to use Gold’s sock with Sabin et al’s gel pack to treat a patient having venous insufficiency as the heat of Sabin et al’s heat pack is not the same as a gel pad. Application of pressure in the instant invention is different from the use of heat in the references. The combination of Gold’s sock and Sabin et al’s gel pack would not result in the structure of the claimed invention. There is no teaching of a pad or structure compatible with compression. A structure for producing heat is not equivalent to structure for receiving or transmitting pressure. In fact, a pack which gives off heat teaches away from a structure which is moldable and which fits into depressions. Contrary to what the examiner says, it is respectfully suggested that a heat pack is not properly combinable for treatment of venous insufficiency.

Issue 4, Claims 1 and 2

Gold has been studied. Gold does not disclose a moldable gel pad. The word “gel” is not used in Gold. A heater pack is not a moldable gel pad and it does not appear from Gold that the reference is using the terms heater pack to mean a moldable gel pad. The heater pack of Sabin is also not a moldable gel pad. The heater pack of Sabin gives off heat and is stiff when giving off heat, and, therefore, it is not moldable when in use. The heater pack of Sabin is not moldable for at least the following reasons: 1) it gives off heat and would not be able to molded when hot due to its increased stiffness at higher temperatures, and 2) at high temperatures it would not be able to touched safely in order to be molded by hand or placed close to the skin.

Claims 1 and 2 are believed to be allowable for the reasons stated above.

Issue 4, Claims 3, 4, and 6

Claim 3 recites a compression stocking and a moldable gel pad in the sleeve of the stocking. Claims 4 and 6 are dependent on claim 3.

Neither Gold nor Sabin disclose a compression stocking. Gold in view of Sabin lacks a compression stocking. In fact, the words “compress”, “compression”, and “stocking” are not even used in the Gold disclosure. Sabin also lacks any teaching, suggestion, or motivation toward a compression stocking, as this reference also lacks the words “compress”, “compression”, and “stocking”. Sabin discloses a heater pack which gives off heat. There is no teaching, suggestion, or motivation in either reference whether used alone or in combination to arrive at or find the claimed compression stocking

structure.

Gold also lacks a moldable gel pad and, as discussed above, Sabin also lacks a moldable gel pad. Sabin discloses a heater pack. However, this pack can not be considered as a moldable gel pad because there is no teaching, suggestion, or motivation in the specification to describe molding or shaping it as in the instant invention. Further, although the heater pack of Sabin can be positioned on the outer circumference of a limb by wrapping it around the limb or by strapping it to a limb or by placing a flat pack in a sleeve around a limb, this is contrary to the concept and meaning of a moldable gel pad of the instant invention which can be shaped to fill in depressions around the ankle of a person to let the stocking apply pressure to reduce venous insufficiency.

There is no teaching, suggestion, or motivation to arrive at the moldable gel pad structure as claimed. Compression stockings are known in the art as set forth in applicant's specification referring to US Patent No. 5,823,195. The sock depicted in Figs. 6 and 7 of Gold is not a compression stocking. Both Gold and Sabin disclose the release of heat. Heat is not the same as pressure. Further, there is no teaching, suggestion, or motivation in Gold in view of Sabin that would allow one of ordinary skill in the art to arrive at the invention of claims 3, 4, and 6.

As a result, claims 3, 4, and 6 are believed to be allowable and are not made obvious by Gold in view of Sabin.

Issue 4, Claim 5

Claim 5, dependent on claim 2, which in turn is dependent on claim 1, recites a stocking including a folded portion and a stitched portion to form a sleeve. The folded and knit portions bound the sleeve in the instant application. Both Gold and Sabin and Gold in view of Sabin lack a sleeve formed by a folded structure. As a result, a prima facie case of obviousness has not been made. Claim 5 is believed to be allowable as it is dependent on allowable claims 1 and 2 as well as for the reasons stated immediately hereinabove.

Issue 4, Claim 8

As demonstrated above, Gold and Sabin do not render claims 3, 4, and 6 unpatentable. Claim 8 depends on claim 6 which depends on claim 4 which depends on claim 3. As a result, claim 8 is believed to be allowable for its dependence on claims 6, 4, and 3 which are allowable.

Claim 8 recites a sleeve which extends 360 degrees within the stocking. Both Gold and Sabin and Gold in view of Sabin lack a sleeve which extends 360 degrees within a stocking. Sabin does not have a stocking. Gold discloses a sock with a pocket 30 in chamber 450. The chamber 450 is located in only one of two set locations and does not extend within 360 degrees of the stocking.

As a result, a proper case of prima facie obviousness has not been made. Gold in view of Sabin does not render claim 8 obvious and, as such, claim 8 is patentable.

Issue 4, Claim 9

Claim 9 recites a device for treating venous insufficiency comprising an understocking having a sleeve and a moldable gel pad within the sleeve. Gold in view of Sabin lacks this structure of an understocking having a sleeve and moldable gel pad within the sleeve. Gold lacks a moldable gel pad and any teaching for using a moldable gel pad to treat venous insufficiency. Sabin also lacks a moldable gel pad. As a result, Gold in view of Sabin lacks any teaching, suggestion, or motivation to arrive at the claimed structure.

Gold further explicitly teaches away from the instant application in suggesting stiffening structure that teaches away from the moldable gel pad of the instant invention. (See col. 8, lines 30-33 and col. 4, line 65- col. 5, line 3). Gold explicitly teaches that the heater pack 34 is activated to produce heat prior to placing the heater pack into the pocket. According, to Sabin in Col. 2, lines 25-41, the activation of the heater pack also stiffens the heater pack. As a result, Gold in view of Sabin would result in the insertion of activated heater pack which is stiff within a sleeve and which is not moldable. This teaches away from the structure of the instant invention which claims a moldable gel pad within a sleeve.

Further, the instant invention teaches an understocking to be used compatibly with a moldable gel pad within a sleeve for treating venous insufficiency. There is no teaching in either reference for using a moldable gel pad to treat venous insufficiency. Both references teach the use of heat. There is no teaching for the gel pad to be moldable and

located within the sleeve of an understocking. In fact, Gold in view of Sabin, teach away from the instant invention in that Sabin teaches the use of a heat pack “around a limb” col. 17, line 20 or on “extensive body surfaces such as the back or chest of a human,” col. 17, lines 26-27. Use of the stiff heater pack structure of Sabin wrapped, strapped or placed in a sleeve around an entire limb would not constitute the claimed structure of a moldable gel pad be used to treat venous insufficiency.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. ‘The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.’ Here, it is respectfully suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the references to arrive at the instant invention as claimed.

As a result, claim 9 is not made obvious by Gold in view of Sabin and claim 9 is allowable.

Issue 4, Claim 10

Claim 10 is dependent on claim 9 and is allowable at least for the reasons stated above. Additionally, claim 10 recites a device for treating venous insufficiency comprising an opening for accessing, placing, and positioning a moldable gel pad within the sleeve.

Both Gold and Sabin separately and when taken together teach away from this device. The heat pack in Sabin may be placed and positioned around the circumference of the wearer's limb (col. 17, lines 12-24 of Sabin) as previously disclosed above. Further, Gold teaches a nylon strap 40 and a sealed chamber 450. Gold lacks the opening for accessing, placing, and positioning a moldable gel pad within the sleeve. Gold teaches in Col. 7, line 32 that: "there is no apparent opening which might mistakenly receive the wearer's foot when the sock is put on." Gold further explicitly teaches away from the instant application in suggesting stiffening structure that teaches away from the moldable gel pad of the instant invention. (See col. 8, lines 30-33 and col. 4, line 65- col. 5, line 3). Gold explicitly teaches that the heater pack 34 is activated prior to placing the heater pack into the pocket. According, to Sabin at col. 2, lines 25-41, the activation of the heater pack will stiffen the heater pack. As a result, Gold in view of Sabin teaches away from the structure of the instant invention. As a result, claim 10 is believed to be allowable and is not made obvious by Gold in view of Sabin.

Issue 4, Claim 11

Claim 11 is dependent on claim 10 and indirectly dependent on claim 9 and is

allowable at least for the reasons that both claims 9 and 10 are allowable. Further, claim 11 recites a compression stocking over the understocking with a sleeve having a pad therein. The claimed structure is totally missing from Gold and Sabin.

The structure of a compression stocking is not properly combinable with the structure of Knox in view of Sabin. As discussed above, there is no teaching, suggestion, or motivation in either reference to use compression with the large heat pack of Sabin.

Most importantly, both references have structural elements that are not properly combinable with a compression stocking and teach away from the compression stocking structure to treat venous insufficiency. Firstly, heat is not equivalent to compression or to the use of a moldable gel pad. The heater pack structures of Gold and Sabin are not properly combinable with compression stocking structure of the instant invention. Combining the heater packs of Gold and Sabin, assuming, *arguendo*, that it could be done, with a compression stocking could result in a severe burn to the skin.

Secondly, both Gold and Sabin teach away from compression. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. A compression stocking would not be able to maximize the transmission of heat as taught in Gold. Secondly, the large heater pack of Sabin which is taught to be applied to an entire limb, would not be conducive to the application of pressure to a specific area of the foot, leg, or ankle to reduce venous insufficiency as in claimed in the instant invention.

It is respectfully submitted that there is no reason a person of ordinary skill in the art would be able to combine the structure of Gold and Sabin to arrive at the structure as claimed. Both Gold and Sabin lack the claimed compression stocking recited in claim 11. Further, the heater packs Gold in Sabin are not compatible nor synonymous with a moldable gel pad held in a compression stocking.

As a result, claim 11 is believed to be allowable for the reasons stated above as well as for its dependence on claim 10.

Issue 4, Claim 12

Claim 12 is dependent on claim 9 and is allowable for at least the reasons that claim 9 is allowable. Additionally, claim 12 recites a compression stocking. Claim 12 is allowable for the same reasons stated above that claim 11 which also recites a compression stocking is allowable. Gold and Sabin as well as Gold in view of Sabin simply lack this structure. A prima facie case of obviousness has not been made.

As a result, Claim 12 is believed to be allowable.

Issue 4, Claim 13

Claim 13 is dependent on claim 9 and is allowable for at least the reasons stated above.

Claim 13 requires an understocking having folded and stitched portions forming a sleeve. The Gold reference in view of Sabin does not disclose the elements or limitations of claim 13. Sabin entirely lacks an understocking having a sleeve. Further, the Gold

reference has a sock with a sealed chamber, but lacks an understocking having a sleeve formed by folded and stitched portions. The words “folded”, “folds”, or “fold” do not appear anywhere in the Gold disclosure. Claim 13 is not made obvious by Gold in view of Sabin and claim 13 is allowable.

Issue 4, Claim 14

Claim 14 is dependent on claim 13 and requires an understocking made from the group of materials selected from nylon, polyester, and cotton. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. Gold teaches the use of materials to maximize the transmission of heat. Increased gaps to allow for increased transmission of heat, in Gold would teach away from the structure of an understocking which fits close to the skin. There is no teaching, suggestion, or motivation found in Gold to result in the structure of the claimed invention. Claim 14 is believed to be allowable for at least the reasons claims 9 and 13 are allowable, as well for the reasons stated above.

Issue 4, Claim 15

Claim 15 recites an understocking made from an elastic material. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. This mesh teaches away from the structure of an understocking made from an elastic material as claimed which would close fitting to the skin and reduce passage of air and transmission of heat. Claim 15 is believed to be allowable for at least

the reasons claims 9 and 13 are allowable, as well for the reasons stated above.

Issue 4, Claim 16-19

Claims 16-19 are method claims for reducing venous insufficiency. Claim 16, as amended, includes the step of “positioning a moldable gel pad about said foot, ankle and leg of said patient to apply pressure to reduce venous insufficiency. “ Neither, Gold Sabin, nor Gold in view of Sabin include the elements of a moldable gel pad for applying pressure. The heater pack in Gold is located in a sealed chamber 450 and attached to a strap 40 for easier exchange of the heater pack. The seal chamber 450 is located on the top of the foot or the bottom of the sock 400. These locations are different and would not apply pressure to reduce venous insufficiency about the foot, ankle or leg. There is no teaching in either reference to apply pressure about the foot, ankle or leg to reduce venous insufficiency. Gold in view of Sabin lacks the claimed moldable gel pad located about the foot, ankle or leg to apply pressure to reduce venous insufficiency.

As stated previously, Gold in view of Sabin lack the claimed moldable gel pad. Further, there is no teaching found in either Gold or Sabin to use a moldable gel pad to apply pressure to reduce venous insufficiency. Further, it would not be possible to apply pressure to reduce venous insufficiency with the heater pack of either reference. The heater pack in Gold is only capable of fitting within a defined chamber location on the foot and is not located or positioned about the leg and ankle to reduce venous insufficiency. Secondly, the heater pack in Sabin is too large to apply pressure to reduce

venous insufficiency. As described in the Sabin disclosure, the heater pack is typically fitted around an entire limb by wrapping it with Velcro, strapping it with tape or putting a flat heater pack in a sleeve around a limb or over a large surface such as the back of the patient. There is no way this large heater pack could be used to apply pressure to reduce the pressure in a small area of the leg or ankle to reduce venous insufficiency. As stated previously, the Gold reference teaches the insertion of an activated heat pack into the chamber, the heater pack of Sabin is stiff when activated, as a result Gold in view of Sabin, would not result in the insertion of moldable gel pack into the understocking. Gold in view of Sabin teaches away from the claimed invention.

Further, the heat pack of Sabin is not equivalent to pressure or even properly combinable to arrive at the structure of the claimed invention. The devices of both Sabin and Gold release heat. The release of heat is not equivalent in any way to the application of pressure or to the use of the claimed moldable gel pad. The release of heat can not be used to reduce venous insufficiency as in the claimed invention.

MPEP section 2143.01 quoted above indicates that the prior art must suggest the desirability of the claimed invention. Here, it is respectfully suggested that there is no basis for combining Gold and Sabin to result in the structure as claimed. Neither Gold nor Sabin teach any of the process steps recited in claims 16-19. Specifically, Gold and Sabin do not teach positioning a moldable gel pad within a sleeve of an understocking worn by a patient. Nor do the references even hint about the understocking being a compression

stocking (claims 18-19) or the overstocking being a compression stocking (claim 17). Sabin's heat pack which is stiff cannot be molded to fit the recesses which are located about an ankle. The moldable gel pad of the claimed invention cannot be replaced by a stiff heat pack. Both references lack structure, teaching, suggestion, and motivation to render the claims obvious.

Gold and Sabin are silent about compression stockings as the understocking or the overstocking and then cannot satisfactorily respond to claims 17-19 in any way.

As a result, claims 16-19 are not made obvious by Gold in view of Sabin.

Issue 4, Claim 21

Claim 21 is dependent on claim 1. Claim 1 is allowable for at least the reasons stated above. In addition claim 21 recites a material that is soft and pliable. The material of the heater pack in Gold in view of Sabin is not soft or pliable. The heater pack of Sabin, when activated, releases heat and stiffens and cannot be bent or reshaped as a pliable material may be bent or reshaped. Once the Sabin's pack is bent, activation occurs, and the heater pack is no longer able to be shaped because of the resulting stiffness and the higher temperature of the heater pack of Sabin. Further, the heater pack of Sabin has a defined form which can not be reshaped easily before or after the exothermic reaction.

Issue 4, Claim 22

Claim 22 is dependent on claim 2 and is allowable for at least the reasons that

claims 1 and 2 are allowable. Claim 22 has elements and limitations not found in Gold or Sabin. Claim 22 recites a stocking which fits over a bodily appendage where the bodily appendage has an exterior surface with surface contours. Claim 22 further recites a moldable gel pad which is small and thin and fits in surface contours of the bodily appendage. Gold and Sabin lack any teaching to apply a moldable gel pad in the surface contours of a bodily appendage. Both Sabin and Gold recite a large device which is located on the outer circumference of a limb. Sabin, in particular, describes using the heating device on a large exterior surface of the body such as the back or the chest. (See Sabin col. 17, line 20 et seq.) Further, both Gold and Sabin lack a moldable gel pad as discussed above. Further, both references also lack a moldable gel pad which is small and thin. Based on the reasons stated above as well as its dependence on claim 2, claim 22 is not made obvious by Gold in view of Sabin, and is allowable.

Issue 4, Claim 23

Claim 23 is dependent on claim 3 and is allowable for at least the reasons that claim 3 is allowable. Claim 23 has further limitations that are not found in Gold in view of Sabin. Claim 23 recites a compression stocking which fits over a bodily appendage with projections. Claim 23 further recites a moldable gel pad which is held in place in proximity to projections of the bodily appendage and provides a desired distribution of pressure between the compression stocking and the bodily appendage. Gold in view of Sabin lacks any teaching to apply a moldable gel pad in proximity to projections of a

bodily appendage. Both Sabin and Gold recite a large device which is located on the outer circumference of a limb. Sabin, in particular, describes using the heating device on a large exterior surface of the body such as the back or the chest. (See Gold Col. 4, lines 56-61 and Sabin col. 17, lns 20 et seq.). Gold recites only two fixed locations for inserting the heater pack. Neither of these locations are near projections of the bodily appendage. Further, these devices cannot be placed in proximity to projections as taught in the instant application.

Further, both references also lack a compression stocking and any teaching, suggestion, or motivation to provide the claimed desired distribution of pressure between the compression stocking and bodily appendage. The references include heater packs which release heat, but they do not provide any teaching with respect to the distribution of pressure. As stated previously, neither reference includes the words “compress” nor “compression” anywhere in their disclosure. Based on the reasons stated above as well as its dependence on claim 3, claim 23 is not made obvious by Gold in view of Sabin, and is allowable.

Issue 4, Claim 24

Claim 24 recites a stocking for use in combination with a bodily appendage where the stocking contains a compartment with a moldable gel pad. The moldable gel pad is placed in proximity to the surface irregularities of the bodily appendage. Gold in view of Sabin does not provide any teaching, suggestion, or motivation to place a moldable gel

pad in proximity to surface irregularities of a bodily appendage. Further, Gold does not contain any teaching, suggestion, or motivation to locate the heater packs near any surface irregularities. The heater pack in Gold is only taught to be located in two locations on the foot and nowhere on the ankle or leg near surface irregularities. The heater device in Sabin locates this large device on the outer circumference of a bodily appendage. There is no teaching, suggestion, or motivation found in either reference or in Gold in view of Sabin to arrive at the structure as claimed. Claim 24 is not made obvious by Gold in view of Sabin. As a result, claim 24 is believed to be allowable.

Issue 5

Whether or not the rejection of Claims 1-6, 8-19, and 21- 24 under 35 USC 103 (a) is correct as being unpatentable over Gold (U.S. Patent No. 5,187,814) and further in view of Beisang III et al (U.S. Patent No. 4,596,250)?

The remarks previously made herein about Beisang are specifically incorporated herein by reference in regard to this rejection without being rewritten herein.

Claims 1-6, 8-19, and 21-24 disclose structure that is different and not found in Gold or Gold in view of Beisang. In the last paragraph of page 5, the Examiner states that: " Gold discloses in Figures 6 and 7 a sock (400) with attached heater pack (34) ... but does not teach a gel pad. Beisang et al discloses a moldable cooling/heating device..." Applicant believes the Examiner is correct in stating that Gold does not teach a gel pad. However, the Examiner states on the top of page 5 that ... "it would have been obvious to

one skilled in the art during the time of invention to use the Beisang, III et al instead as such would be not only environmentally friendly but also economically sound.“

Whether this combination can be made is irrelevant as it would still not result in the structure as claimed. Both references teach the use of a heat pack; a pack that supplies heat has nothing to do with the instant invention. A stiff pack that supplies heat in the reference is structurally different from a moldable gel pad that can be compressed and molded safely near the surface of the skin. The invention of the instant application claims a moldable gel pad, both references teach “a pack”. A heat pack is not a moldable gel pad. As a result, the invention of the instant application is not made obvious, by Gold in view of Beisang, and claims 1-6, 8-19, and 21-24 are patentable.

Further, applicant strongly disagrees with the Examiner’s statement on page 5, line 10. The Examiner states that: ” The Gold device would be capable of performing the method of treating a patient having venous insufficient via Gold’s sock using Sabin [sic] et al’s gel pack. “ It would not be possible to use Gold’s sock with Beisang et al’s gel pack to treat a patient having venous insufficiency. As the heat of Beisang et al’s heat/cooling pack is not the same as a moldable gel pad. Application of pressure in the instant invention is different from the use of heat in the references. The combination of Gold’s sock and Beisang et al’s gel pack will not result in the structure of the claimed invention. There is no teaching of a moldable gel pad or structure compatible with compression. Structure for producing heat is not equivalent to structure for receiving

pressure and transmitting pressure, ie, a moldable gel pack where needed. In fact, a pack which gives off heat teaches away from a structure which can be molded as desired. Contrary to what the examiner says, a heat pack is not properly combinable with treatment of venous insufficiency.

Compression stockings are known in the art as set forth in applicant's specification referring to US Patent No. 5,823,195. The sock depicted in Figs. 6 and 7 of Gold is not a compression stocking. As discussed above, Beisang also lacks a moldable gel pad. Both Gold and Beisang disclose structure for the release of heat. Heat is not the same as compression. Further, there is no teaching, suggestion, or motivation in Gold in view of Beisang that would allow one of ordinary skill in the art to arrive at the invention as claimed.

Issue 5, Claims 1 and 2

Gold has been studied. Gold does not disclose a moldable gel pad. The word "gel" is not used in Gold. A heater pack is not a moldable gel pad and it does not appear from Gold that the reference is using the terms heater pack to mean a moldable gel pad. The heater pack of Beisang is also not a moldable gel pad. Beisang discloses a moldable cooling/heating device used for cooling/heating body organs or parts.

Beisang's invention is directed primarily to cooling organs of a human body, so that they can be treated. It is known that cooling an organ slows its metabolism and enables more effective treatment of the organ and the patient. So, Beisang enables this by

providing a moldable pillow type device that can hug the shape of an organ to be operated on during surgery without taking energy away from the other organs. Further, with Beisang it is necessary that the temperature be controlled, so that the patient does not, in effect, get freezer burn.

There is no teaching, suggestion, or motivation to combine Gold with Beisang to result in the structure as claimed. Beisang provides a resting surface for an organ. Beisang teaches maximizing the cooling surface area in contact with the organ such as by wrapping it around more of the organ. Beisang also teaches that body tissue can be damaged from extremely hot or cold temperatures, col. 3, lines 40-42. The storage medium in Beisang changes from semisolid to liquid form. There is no teaching to combine the sterilizable surface heat pack of Beisang in a sleeve or a stocking where it is no longer in direct contact with the organ. Claims 1 and 2 are believed to be allowable for the reasons stated above.

Issue 5, Claims 3, 4, and 6

Claim 3 recites a compression stocking and a moldable gel pad within a sleeve of the compression stocking. Claims 4 and 6 are dependent on claim 3.

Gold and Gold in view of Beisang both lack a compression stocking. In fact, the words “compress”, “compression”, and “stocking” are not even used in the Gold disclosure. Beisang also lacks any teaching, suggestion, or motivation towards a compression stocking, as this reference also lacks the words “compress”, “compression”,

and “stocking”. Beisang discloses a heater pack which gives off heat. There is no teaching, suggestion, or motivation in either reference whether used alone or in combination to arrive at the missing compression stocking structure.

Gold also lacks a moldable gel pad and as discussed above Beisang also lacks a moldable gel pad. Beisang discloses a heater pack. However, this pack can not be considered as a moldable gel pad because there is no teaching, suggestion, or motivation contained in the specification to describe molding or shaping it as in the instant invention. Further, the heater pack of Beisang has a shape with defined outer boundaries. One side of the heater pack of Beisang is moldable and the other side opposite of the organs is not flexible as it does not have to be flexible for the intended applications. Beisang indicates that a large heater/cooling pack can be positioned on the outer circumference of a limb. This is contrary to the moldable gel pad of the instant invention which can be shaped and does not have a large outer perimeter. The moldable gel pad placed in the sleeve of a compression stocking of the claimed invention serves to apply pressure to a patient in places where the pressure is needed to treat venous insufficiency. Beisang’s heater cannot be substituted for the moldable gel pad.

There is no teaching, suggestion, or motivation to arrive at the moldable gel pad structure as claimed.

As a result, claims 3, 4, and 6 are believed to be allowable and are not made obvious by Gold in view of Beisang.

Issue 5, Claim 5

Claim 5 dependent on allowable claim 2 which in turn is dependent on allowable claim 1 recites a stocking including a folded portion and a stitched portion to form a sleeve. The folded and knit portions bound the sleeve in the instant application. Both Gold and Beisang and Gold in view of Beisang lack a sleeve formed by a folded structure. As a result, a proper case of prima facie obviousness has not been made. Claim 5 is believed to be allowable.

Issue 5, Claim 8

As demonstrated above, Gold and Beisang do not render claims 3, 4, and 6 unpatentable. Claim 8 is believed allowable for its dependence on claims 6, 4, and 3 which are allowable.

Claim 8 recites the following structure which is not found in Gold in view of Beisang: a sleeve which extends 360 degrees within the stocking. Both Gold and Beisang and Gold in view of Beisang lack a sleeve which extends 360 degrees within a stocking. Sabin does not have a stocking. Gold discloses a sock with a pocket 30 in chamber 450. The chamber 450 has a fixed location and does not extend 360 degrees within the stocking.

As a result, a proper prima facie obviousness rejection has not been made. Gold in view of Beisang does not render the instant application obvious and claim 8 is believed to be patentable.

Issue 5, Claim 9

Claim 9 recites a device for treating venous insufficiency comprising an understocking having a sleeve and a moldable gel pad within the sleeve. Gold in view of Beisang lacks this structure of an understocking having a sleeve and moldable gel pad within the sleeve. The Gold reference lacks a moldable gel pad and lacks any disclosure of a moldable gel pad to treat venous insufficiency. Beisang also lacks a moldable gel pad as disclosed at length above. As a result, Gold in view of Beisang lacks the required teaching, suggestion, or motivation to arrive at the claimed structure.

Gold further explicitly teaches away from the instant application in suggesting stiffening structure which differs significantly from the moldable gel pad of the instant invention. (col. 4 , line 65 - col. 5, line 3). Gold explicitly teaches that the heater pack 34 is activated prior to placing the heater pack into the pocket. As a result, Gold in view of Beisang would result in the insertion of a stiff heater pack which is inserted within a sleeve and at a temperature where it would not be moldable. This teaches away from the structure of the instant invention which claims a moldable gel pad within a sleeve.

Further, the instant invention teaches an understocking to be used compatibly with a moldable gel pad within a sleeve for treating venous insufficiency. There is no teaching in either reference for using a moldable gel pad to treat venous insufficiency. Both references teach the use of heat with no teaching whatsoever towards venous insufficiency. Further, there is no teaching for the gel pad to be moldable and be located

within the sleeve of an understocking. In fact, Gold in view of Beisang, teaches away from the instant invention, in that Beisang teaches the use of a heat pack “around a limb” col. 17, line 20 or on “extensive body surfaces such as the back or chest of a human” col. 17, lines 26-27. Use of the large heater pack structure of Beisang around an entire limb would not enable a moldable gel pad be used to treat venous insufficiency.

Use of the Beisang heating/cooling pack in the winter in northern climates may result in freezing the pack at low temperatures thus defeating the function of treating venous insufficiency. This is assuming that somehow the heating/cooling pack could be crammed face forward into the sleeve of applicant’s claimed invention. Even if Beisang were somehow crammed into the sleeve of the instant invention it is doubtful that the lack of symmetry of the Beisang heater would work. One side of the Beisang heater is heat-resistant and less pliable than the moldable side of the device which is usually used to cool organs.

Further, the heat of Gold in view of Beisang could not be used for treating venous insufficiency as it would not have the required effect to reduce venous insufficiency.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. ‘The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.’ Here, it is respectfully suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the references to arrive at the instant invention as claimed.

As a result, claim 9 is not made obvious by Gold in view of Beisang and claim 9 is allowable.

Issue 5, Claim 10

Claim 10 is dependent on claim 9 and is allowable at least for the reasons stated above as well as for the additional claimed structure recited in claim 10. Claim 10 recites a device for treating venous insufficiency comprising an opening for accessing, placing, and positioning a moldable gel pad within the sleeve.

Both Gold and Beisang separately and when taken together teach away from this device. As the heat pack in Beisang is large, it is placed and positioned around the circumference of the wearer’s limb (col. 17, lines 12-24 of Beisang) as expressed above. Further, Gold teaches a nylon strap 40 and a sealed chamber 450. Gold lacks the opening for accessing, placing, and positioning a moldable gel pad within the sleeve. Gold teaches in col. 7, line 32 that: “there is no apparent opening which might mistakenly receive the wearer’s foot when the sock is put on.” Gold further explicitly teaches away from the

instant application in suggesting stiffening structure that teaches away from the moldable gel pad of the instant invention. (See col. 8, lines 30-33 and col. 4 , line 65- Col. 5, line 3). Gold explicitly teaches that the heater pack 34 is activated to produce heat prior to placing the heater pack into the pocket. According, to Beisang in col. 2, lines 25-41, the activation of the heater pack will stiffen the heater pack. As a result, Gold in view of Beisang teaches away from the structure of the instant invention.

As a result, claim 10 is believed to be allowable and is not made obvious by Gold in view of Beisang.

Issue 5, Claim 11

Claim 11 is dependent on claim 10 and indirectly dependent on claim 9 and is allowable at least for the reasons that both claims 9 and 10 are allowable. Further, claim 11 recites a compression stocking residing over the understocking. This structure is totally missing from Gold and Beisang. The claimed compression over stocking is not properly combinable with the structure of Gold in view of Beisang. As discussed above, there is no teaching, suggestion, or motivation in either reference to use compression stockings with the large heat pack of Beisang. It is respectfully urged that Beisang will not work with the claimed invention as set forth in claim 11 because it is not moldable and is structurally much different.

Most importantly, both references have structural elements that are not properly combinable with a compression over stocking and teach away from the compression over

stocking structure to treat a venous insufficiency. Firstly, heat is not equivalent to compression or moldability of a gel pad. The heater pack structures of Gold and Beisang are not properly combinable with compression stocking structure of the instant invention. Combining the heater packs of Gold and Beisang with a compression stocking could result in a severe burn to the skin.

Secondly, both Gold and Beisang teach away from compression. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. A compression stocking would not be able to maximize the thermal transmission as taught in Beisang. Secondly, the large heater pack of Beisang which is taught to be applied to an entire limb by wrapping it, strapping, or placing in a flat position in a sleeve, would not be conducive to the application of pressure to a specific area of the foot, leg, or ankle to reduce venous insufficiency as in the instant invention.

It is respectfully urged that there is no reason a person of ordinary skill in the art would be able to combine the structure of Gold and Beisang to arrive at the structure as claimed. Both Gold and Beisang lack the compression stocking structure of the instant invention. Further, the heater pack structures of Gold in Beisang are not compatible with a moldable gel pad held in a compression stocking.

As a result, claim 11 is believed to be allowable for the reasons stated above as well as for its dependence on claim 10.

Issue 5, Claim 12

Claim 12 is dependent on claim 9 and is allowable for at least the reasons that claim 9 is allowable. Additionally, claim 12 recites a compression stocking. Claim 12 is allowable for the same reasons stated above in regard to claim 11. The arguments made above in regard to claim 11 insofar as the compression stocking is concerned are incorporated herein by reference without repeating them herein. Gold and Beisang as well as Gold in view of Beisang simply lack the claimed compression over stocking.

As a result, Claim 12 is believed to be allowable.

Issue 5, Claim 13

Claim 13 is dependent on claim 9 and is allowable for at least the reasons stated above.

Claim 13 requires an understocking having folded and stitched portions forming a sleeve. The Gold reference in view of Beisang does not disclose the elements or limitations of claim 13. Beisang entirely lacks an understocking having a sleeve. Further, the Gold reference has a sock with a sealed chamber, but lacks an understocking having a sleeve formed by folded and stitched portions. The words “folded”, “folds”, or “fold” do not appear anywhere in the Gold disclosure.

Claim 13 is not made obvious by Gold in view of Beisang and claim 13 is allowable.

Issue 5, Claim 14

Claim 14 is dependent on claim 13 and requires an understocking made from the

group of materials selected from nylon, polyester, and cotton. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. Gold teaches the use of materials to maximize the transmission of heat. Increased gaps to allow for increased transmission of heat as expressed in Gold would teach away from the structure of an understocking which necessarily fits close to the skin and is implied by the claim. There is no teaching, suggestion, or motivation found in Gold to result in the structure of the claimed invention.

Claim 14 is believed to be allowable for at least the reasons claims 9 and 13 are allowable, as well for the reasons stated above.

Issue 5, Claim 15

Claim 15 recites an understocking made from an elastic material. In col. 5, line 55 et seq., Gold teaches the use of a mesh material to allow free passage of air to maximize heat transmission. This mesh teaches away from the structure of an understocking made from an elastic material as claimed in the instant invention which would be close fitting to the skin and reduce passage of air and transmission of heat.

Claim 15 is believed to be allowable for at least the reasons claims 9 and 13 are allowable, as well for the reasons stated above.

Issue 5, Claim 16-19

All remarks made hereinabove in regard to the deficiencies of Beisang are incorporated herein by reference with rewriting them herein.

Claims 16-19 are method claims for reducing venous insufficiency. Claim 16, as amended, includes the step of “positioning a moldable gel pad about said foot, ankle and leg of said patient to apply pressure to reduce venous insufficiency.” Neither, Gold Beisang, nor Gold in view of Beisang include the elements of a moldable gel pad for applying pressure. The heater pack in Gold is located in a sealed chamber 450 and attached to a strap 40 for easier exchange of the heater pack. The seal chamber 450 is located on the top of the foot or the bottom of the sock 400. These locations are fixed and different from the claimed invention and thus pressure cannot be applied to reduce venous insufficiency in specific locations about the ankle or leg where pressure must be applied. There is no teaching in either reference to apply pressure about the ankle or leg to reduce venous insufficiency. Gold in view of Beisang lacks the structure of a moldable gel pad located about the foot, ankle or leg to apply pressure to reduce venous insufficiency.

As stated previously, Gold in view of Beisang lacks a moldable gel pad. Further, there is no teaching found in either Gold or Beisang to use a moldable gel pad to apply pressure to reduce insufficiency.

Further, it would not be possible to apply pressure to reduce venous insufficiency with the heater pack of either reference. The heater pack in Gold is only fits in a specific chamber location on the foot and is not located in the position on the leg and ankle necessary to reduce venous insufficiency. Secondly, the heater pack in Beisang is too large to apply pressure to reduce venous insufficiency. As described in the Beisang

disclosure, the heater pack is typically fit around an entire limb via wrapping it, strapping it or sticking a flat pack in a sleeve or it can be placed over a large surface such as the back. As a result, Beisang's large heater pack could not be used to apply pressure to reduce the pressure in a small area of the leg or ankle to effectively treat venous insufficiency.

As stated previously, the Gold reference teaches the insertion of an activated heat pack into a fixed chamber, as a result Gold in view of Beisang, would not result in the insertion of moldable gel pack into the understocking. Gold in view of Beisang teaches away from the claimed invention.

Further, the heat pack of Beisang is not equivalent to pressure. Beisang's heat pack is not equivalent to a moldable gel pad. Beisang is not believed to be properly combinable to arrive at the structure of the claimed invention. The devices of both Beisang and Gold release heat. The release of heat is not equivalent in any way to the application of pressure. The release of heat can not be used to reduce venous insufficiency as in the claimed invention.

MPEP section 2143.01 quoted above indicates that the prior art must suggest the desirability of the claimed invention. Here, it is respectfully suggested that there is no basis for combining Gold and Beisang to result in the structure as claimed. Neither Gold nor Beisang teach any of the process steps recited in claims 16-19. Specifically, Gold and Beisang do not teach positioning a moldable gel pad within a sleeve of an understocking

worn by a patient (claim 16). Nor do the references even hint about the under stocking being a compression stocking (claims 18-19) or the overstocking being a compression stocking (claim 17). Beisang's heat pack which is stiff cannot be molded to fit the recesses which are located about an ankle. The moldable gel pad of the claimed invention cannot be replaced by a stiff heat pack. Both references lack structure, teaching, suggestion, and motivation to render the claims obvious. As a result, claims 16-19 are not made obvious by Gold in view of Beisang.

Issue 5, Claim 21

Claim 21 is dependent on claim 1. Claim 1 is allowable for at least the reasons stated above. In addition, claim 21 recites a material that is soft and pliable. The material of the heater pack in Gold and Beisang is not soft or pliable. The heater packs of Gold and Beisang are not able to be bent and reshaped as expected from a pliable material. Once the material is bent, activation occurs, and the heater pack is no longer able to be shaped because of the resulting stiffness (in the case of Gold) and the higher temperature of the heater pack of Beisang renders it useless or harmful to treat venous insufficiency with potentially burning heat placed and kept close to the skin. Further, the heater pack of Beisang is not symmetrical and has one thermally resistant side which is not as pliable as the moldable side which sets up additional problems and considerations if the heater pack of Beisang is crammed into the sleeve of the stocking of the instant invention.

Issue 5, Claim 22

Claim 22 is dependent on claim 2 and is allowable for at least the reasons that claim 2 is allowable. Claim 22 has further limitations that are not found in Knox in view of Beisang. Claim 22 recites a stocking which fits over a bodily appendage where the bodily appendage has an exterior surface with surface contours. Claim 22 further recites a moldable gel pad which is small and thin and fits in surface contours of a bodily appendage. Gold in view of Beisang lacks any teaching to apply a moldable gel pad in the surface contours of a bodily appendage. Both Beisang and Gold recite a large device which is located on the outer circumference of a limb. Beisang, in particular, describes using the heating device on a large exterior surface of the body such as the back or the chest. (See Gold col. 4, lines 56-61 and Beisang col. 17, line 25) Further, both Gold and Beisang lack a moldable gel pad as discussed above. Further, both references also lack a moldable gel pad which is small and thin.

Based on the reasons stated above as well as its dependence on claim 2, claim 22 is not made obvious by Gold in view of Beisang, and is allowable.

Issue 5, Claim 23

Claim 23 is dependent on claim 3 and is allowable for at least the reasons that claim 3 is allowable. Claim 23 has further limitations that are not found in Gold in view of Beisang. Claim 23 recites a compression stocking which fits over a bodily appendage where the bodily appendage has projections. Claim 23 further recites a moldable gel pad which is held into place in proximity to projections of the bodily appendage and provides

a desired distribution of pressure between the compression stocking and the bodily appendage. Gold in view of Beisang lacks any teaching to apply a moldable gel pad in proximity to projections of a bodily appendage. Both Beisang and Gold recite a pack which is located on the outer circumference of a limb. Beisang, in particular, describes using the heating device on a large exterior surface of the body such as the back or the chest. (See Gold col. 4, lines 56-61 and Beisang col. 17, line 25).

Gold recites two fixed locations for inserting the heater pack. Both of these locations are fixed and neither are near projections of the bodily appendage. Further, these devices would not be able to be placed in proximity to projections as taught in the instant application.

Further, both references also lack a compression stocking and any teaching, suggestion, or motivation to provide the claimed desired distribution of pressure between the compression stocking and bodily appendage. The references include heater packs which release heat, but they do not provide any teaching with respect to the distribution of pressure. As stated previously, neither reference includes the words “compress” nor “compression” anywhere in their disclosure.

Based on the reasons stated above as well as its dependence on claim 3, claim 23 is not made obvious by Gold in view of Beisang, and is allowable.

Issue 5, Claim 24

Claim 24 recites a stocking for use in combination with a bodily appendage where

the stocking contains a compartment with a moldable gel pad. The moldable gel pad is placed in proximity to the surface irregularities of the bodily appendage. Gold in view of Beisang does not provide any teaching, suggestion, or motivation to place a moldable gel pad in proximity to surface irregularities of a bodily appendage. Further, Gold does not contain any teaching, suggestion, or motivation to locate the heater packs near any surface irregularities. The heater pack in Gold is located in two locations on the foot and nowhere on the ankle or leg near surface irregularities. The heater device in Beisang locates this large device on the outer circumference of a bodily appendage. There is no teaching, suggestion, or motivation found in either reference or in Gold in view of Beisang to arrive at the structure as claimed.

Claim 24 is not made obvious by Gold in view of Beisang. As a result, claim 24 is believed to be allowable.

Issue 6

Whether or not the rejection of Claim 7 under 35 U.S.C. 103 (a) as being unpatentable over Gold (U.S. Patent No. 5,187,814), modified by Sabin, et al. (U.S. Patent No. 5,984,953), and further in view of Lyles (U.S. Patent No. 6,001,122)?

Issue 6, Claim 7

Claim 7 is dependent on claims 2 and 5 and is allowable for at least the reasons claims 2 and 5 are allowable. Namely, claim 2 recites a moldable gel pad and claim 5 recites a folded portion to form a sleeve. Gold modified by Sabin and in further view of

Lyles lacks both of these claimed elements.

As demonstrated above, Gold clearly lacks the elements of the instant invention and contains teaching contrary to the instant invention. Gold is not properly combinable with Sabin to arrive at the invention recited in claim 7. The disposable heat pack of Sabin is not the equivalent of a moldable gel pad. Lyles appears to be a wrap around device with a hot or cold pack wrapped around a stocking. The word “stocking” is not used in Lyles. The device in Lyles is not a stocking and it does not extend 360 degrees around the foot of a user. The term “360” does not appear in Lyles. Rather, each closed edge is in the form of a pleat 23.

Gold is not properly combinable with Sabin in view of Lyles to arrive at the invention recited in claim 7. Lyles appears to be a device with two pockets for holding thermal packs. (See Lyles Col. 1, lines 56-67.) As with the chambers in Gold, these pockets are found in only two locations of the device. Further, “During use, each thermal pack is placed within a pocket. (See Lyles Col. 4, lines 4-5). As a result, these locations are limited to hold the thermal packs in only two locations on the foot.

The Examiner states that the pockets (18) are mounted on the sleeve (18) of the bootie (10) with both a top pocket (18) and a bottom pocket (22). Applicant disagrees with the Examiner that these pockets extend 360° degrees within the sock. As set forth in Lyles, Col. 1, line 57 et seq. each pocket has a rectangular configuration, walls, and are mounted on the top and bottom of the bootie. The walls of the pockets which hold the

thermal packs prevent the pockets extending within 360 the stocking. These pockets can not be considered to extend 360° with the stocking as they are located on the top and bottom and have walls.

Gold and Lyles disclose pockets. The pockets are limited to only one portion of the device. The sleeve recited in claim 7 is concentric with the stocking and is formed continuously about the stocking, for example, it extends 360° within the stocking. (See for example Figs. 1 and 7 of Shook et al.) Gold, Lyles, and Sabin whether used alone or in combination lack a stocking with a sleeve which extends 360 degrees around stocking for accessing, positioning, and positioning a moldable gel pad. Claim 7 is not made obvious by Gold, modified by Sabin, and further in view of Lyles and as a result claim 7 is believed to be allowable.

Issue 7:

Whether or not the rejection of Claim 7 under 35 U.S.C. 103 (a) is correct as being unpatentable over Gold (U.S. Patent No. 5,187,814), modified by Beisang, III et al. (U.S. Patent No. 4,596,250), and further in view of Lyles (U.S. Patent No. 6,001,122)?

Issue 7, Claim 7

Claim 7 is dependent on claims 2 and 5 and is allowable for at least the reasons claims 2 and 5 are allowable. Namely, claim 2 recites a moldable gel pad and claim 5 recites a folded portion to form a sleeve. Gold modified by Beisang and in further view of

Lyles lacks both of these claimed elements.

As demonstrated above, Gold clearly lacks the elements of the instant invention and contains teaching contrary to the instant invention. Gold is not properly combinable with Beisang to arrive at the invention recited in claim 7. Lyles appears to be a wrap around device with a hot or cold pack wrapped around a stocking. The word “stocking” is not used in Lyles. The device in Lyles is not a stocking and it does not extend 360 degrees around the foot of a user. The term “360” does not appear in Lyles. Rather, each closed edge is in the form of a pleat 23.

Gold is not properly combinable with Beisang in view of Lyles to arrive at the invention recited in claim 7. Lyles appears to be a device with two pockets for holding thermal packs. (See Lyles Col. 1, lines 56-67.) As with the chambers in Gold, these pockets are found in only two locations of the device. Further, “During use, each thermal pack is placed within a pocket. (See Lyles Col. 4, lines 4-5). As a result, these locations are limited to hold the thermal packs in only two locations on the foot.

The Examiner states that the pockets (18) are mounted on the sleeve (18) of the bootie (10) with both a top pocket (18) and a bottom pocket (22). Applicant disagrees with the Examiner that these pockets extend 360° degrees within the sock. As set forth in Lyles, Col. 1, line 57 et seq. each pocket has a rectangular configuration, walls, and are mounted on the top and bottom of the bootie. The walls of the pockets which hold the thermal packs prevent the pockets extending within 360 the stocking. These pockets can

not be considered to extend 360° with the stocking as they are located on the top and bottom and have walls.

Gold and Lyles disclose pockets. The pockets are limited to only one portion of the device. The sleeve recited in claim 7 is concentric with the stocking and is formed continuously about the stocking, for example, it extends 360° within the stocking. (See for example Figs. 1 and 7 of Shook et al.) Gold, Lyles, and Beisang whether used alone or in combination lack a stocking with a sleeve which extends 360 degrees around stocking for accessing, positioning, and positioning a moldable gel pad. Claim 7 is not made obvious by Gold, modified by Beisang, and further in view of Lyles and as a result claim 7 is believed to be allowable.

SUMMARY AND CONCLUSION

Applicant claims structure that is different and not made obvious by the references cited by the Examiner. Claims 1-19 and 21-24 are allowable. Consideration of claims 1-19 and 21-24 is requested.

Claims 1, 2, 5, 7, 9-15, 22, and 24 are patentable over Knox in view of Sabin et al for the reasons stated above. Claims 1, 2, 5, 7, 9-15, 22, and 24 are patentable over the Knox in view of Beisang for the reasons stated above. Claims 1-6, 8-19, and 21- 24 are patentable over Gold in view of Sabin et al for the reasons stated above. Claims 1-6, 8-19, and 21- 24 are patentable over Gold in view of Beisang for the reasons stated above.

Claim 7 is patentable over Gold modified by Sabin and further in view of Lyles for

the reasons stated above. Claim 7 is patentable over Gold modified by Beisang and further in view of Lyles for the reasons stated above.

Reconsideration of claims 1-19 and 21-24 is respectfully requested.

Wherefore, it is respectfully requested that the rejection of the claims be reversed and that the same be determined as being allowable.

FEE

If there any additional charges, or any overpayment, in connection with the filing of this appeal brief, the Commissioner is hereby authorized to charge any such deficiency, or credit any such overpayment, to deposit account no. 23-3060.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants: C. David SHOOK

Title: UNDERSTOCKING WITH SLEEVE FOR POSITIONING A GEL PAD

Filing Date: June 25, 2003

Serial No.: 10/603,643

Examiner: Camtu Tran NGUYEN

Group Art Unit: 3743

Attorney Docket No. 8142A

September 14, 2007

Commissioner for Patents
P. O. Box 1450
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CLAIMS APPENDIX

Claims:

1. A stocking comprising a sleeve and a moldable gel pad within said sleeve.
2. A stocking as claimed in claim 1 further comprising an opening in said sleeve for accessing, placing and positioning said moldable gel pad within said sleeve.
3. A compression stocking comprising a sleeve and a moldable gel pad within said sleeve.

4. A compression stocking as claimed in claim 3 further comprising an opening in said sleeve for accessing, placing and positioning said moldable gel pad within said sleeve.

5. A stocking as claimed in claim 2 wherein said stocking includes a folded portion and a stitched portion to form said sleeve.

6. A compression stocking as claimed in claim 4 wherein said compression stocking includes a folded portion and a stitched portion to form said sleeve.

7. A stocking as claimed in claim 5 wherein said sleeve extends 360 degrees within said stocking.

8. A compression stocking as claimed in claim 6 wherein said sleeve extends 360 degrees within said stocking.

9. A device for treating venous insufficiency comprising an understocking having a sleeve and a moldable gel pad within said sleeve.

10. A device for treating venous insufficiency as claimed in claim 9 further comprising an opening in said sleeve for accessing, placing and positioning said moldable gel pad within said sleeve.

11. A device for treating venous insufficiency as claimed in claim 10 further comprising a compression stocking residing over said understocking.

12. A device for treating venous insufficiency as claimed in claim 9 further comprising a compression stocking residing over said understocking.

13. A device for treating venous insufficiency as claimed in claim 9 wherein said understocking includes a folded portion and a stitched portion forming said sleeve.

14. A device for treating venous insufficiency as claimed in claim 13 wherein said understocking is made from a material selected from the group of nylon, polyester, and cotton.

15. A device for treating venous insufficiency as claimed in claim 13 wherein said understocking is made from a material selected from an elastic material.

16. A method of treating a patient having venous insufficiency comprising the steps of:

applying an understocking having a sleeve onto the foot, ankle and leg of said patient;

inserting a moldable gel pad into said sleeve; and,

positioning said moldable gel pad about said foot, ankle and leg of said patient to apply pressure to reduce said venous insufficiency.

17. A method of treating a patient having venous insufficiency as claimed in claim 16 further comprising the steps of:

applying a compression stocking over said understocking and said moldable gel pad.

18. A method of treating a patient having venous insufficiency as claimed in claim 16 wherein said understocking is a compression stocking.

19. A method of treating a patient having venous insufficiency as claimed in claim 17 wherein said understocking is a compression stocking.

20. (Cancelled)

21. A stocking as claimed in claim 1 where said moldable gel pad is comprised of a material that is soft and pliable.

22. A stocking as claimed in claim 2 wherein said stocking fits over a bodily appendage; said bodily appendage has an exterior surface; said exterior surface has surface contours; and, said moldable gel pad is small and thin; said moldable gel pad is placed in said sleeve in proximity to said surface contours; said moldable gel pad inserted into a compression stocking and held in a fixed position close to the surface of the skin; and, said moldable gel pad is fit in said surface contours of said appendage.

23. A compression stocking as claimed in claim 3 wherein said stocking is placed over a bodily appendage; said bodily appendage has projections; said moldable gel pad is held into place in a location in proximity to said projections of said bodily appendage to provide the desired distribution of pressure between said compression stocking and said bodily appendage.

24. A stocking for use in combination with a bodily appendage, said bodily appendage has surface irregularities, said surface irregularities include bony prominences and recesses, said stocking includes a compartment and a moldable gel pad; and, said moldable gel pad positioned in proximity to said surface irregularities.

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EVIDENCE APPENDIX

NONE

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RELATED PROCEEDINGS APPENDIX

NONE